

REMARKS

Claims 1-13, 15, 16 and 18-31 are pending in the application. Claims 1-9 and 18-29 have been withdrawn. As no amendments are made herein, no new matter has been added.

Rejections Under 35 USC § 103

Further to the arguments presented in the Supplemental Response filed September 7, 2010, Applicants present the following additional arguments.

The Examiner has rejected claims 10-13, 15, 16, and 30 under 35 U.S.C. § 103 as unpatentable over Kirker-Head and further in view of Wikesjö, Tsuboi, Kurihara, and Harada.

Applicants reiterate that that the combination of BDNF and hyaluronic acid provided an unexpectedly significantly improved cementum generation as compared to the use of HMW-HA alone or BDNF with poly(lactic acid-co-glycolic acid)(PLGA).

Applicants herein provide a further Declaration of Dr. Kurihara (Kurihara Declaration III) showing in an in vivo model that BDNF + HMW-HA demonstrate significantly increased bone area and cementum length compared to the HMW-HA group. *See* Fig. YB (or 6B), submitted with the amendment of September 7, 2010 as Figure 1.

In the Kurihara Declaration III, pictures and methods are provided which describe the in vivo model with which the morphological analysis data was achieved.

Dr. Kurihara concludes that the effects of the present methods are unexpected. Specifically, Dr. Kurihara states:

it is clear that the presence of both BDNF and HA causes the significantly increased bone area and increased cementum length. In contrast, neither the BDNF on PLGA or HMW-HA carrier alone caused a significant increase in bone area or cementum length. In short, neither BDNF nor HMW-HA alone is responsible for the significant improvement in periodontal regeneration.

Moreover, it is clear that using a different combination of BDNF and carrier does not result in the significant increase in bone area or cementum growth.

Thus, Applicants submit that the Kurihara Declaration III presents evidence of unexpected results which is sufficient to overcome the obviousness rejection based on the combined cited references.

In conclusion, the Examiner has not made a proper case of *prima facie* obviousness. Consequently, Applicants respectfully request withdrawal of the rejections.

Conclusion

In view of the above, all of the claims are submitted as defining non-obvious, patentable subject matter. Removal of the rejections and allowance of the claims are respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Susan W. Gorman, Ph.D., Reg. No. 47,604 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By  #47,604

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Enclosure: Kurihara Declaration III